

WHAT IS CLAIMED IS:

1. An isolated polynucleotide encoding a polypeptide having an amino acid sequence of SEQ ID NO:2.
- 5 2. The polynucleotide of claim 1, wherein said polynucleotide comprises a nucleic acid sequence of SEQ ID NO:1 or a complement thereof.
- 10 3. The polynucleotide of claim 2, wherein said polynucleotide further comprises a promoter operable in eukaryotic cells.
4. The polynucleotide of claim 3, wherein said promoter is heterologous to the coding sequence.
- 15 5. A isolated and purified nucleic acid that hybridizes, under high stringency conditions, to a DNA segment comprising about 102 to 1279 bases of SEQ ID NO:1.
- 20 6. A nucleic acid of about 15 to about 5000 base pairs comprising at least 102 contiguous base pairs of SEQ ID NO:1, or the complement thereof.
7. A isolated and purified nucleic acid that hybridizes, under high stringency conditions, to a DNA segment comprising about 15 to 700 bases of SEQ ID NO:18.
- 25 8. A isolated and purified nucleic acid that hybridizes, under high stringency conditions, to a DNA segment comprising about 15 to 478 bases of SEQ ID NO:20.

9. A nucleic acid of about 15 to about 5000 base pairs comprising about 15 contiguous base pairs of SEQ ID NO:18 or SEQ ID NO:20, or the complement thereof.
- 5 10. The nucleic acid of claim 9, comprising about 20 contiguous base pairs of SEQ ID NO:18 or SEQ ID NO:20, or the complement thereof.
11. The nucleic acid of claim 9, comprising about 30 contiguous base pairs of SEQ ID NO:18 or SEQ ID NO:20, or the complement thereof.
- 10 12. The nucleic acid of claim 9, comprising about 50 contiguous base pairs of SEQ ID NO:18 or SEQ ID NO:20, or the complement thereof.
13. The nucleic acid of claim 9, comprising about 100 contiguous base pairs of SEQ ID NO:18 or SEQ ID NO:20, or the complement thereof.
- 15 14. The nucleic acid of claim 9, comprising about 150 contiguous base pairs of SEQ ID NO:18 or SEQ ID NO:20, or the complement thereof.
- 20 15. The nucleic acid of claim 9, comprising about 250 contiguous base pairs of SEQ ID NO:18 or SEQ ID NO:20, or the complement thereof.
16. The nucleic acid of claim 9, comprising about 478 contiguous base pairs of SEQ ID NO:18 or SEQ ID NO:20, or the complement thereof.
- 25 17. The nucleic acid of claim 9, comprising about 550 contiguous base pairs of SEQ ID NO:18, or the complement thereof.
18. The nucleic acid of claim 9, comprising 700 contiguous base pairs of SEQ ID NO:18, or the complement thereof.
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19. A peptide comprising at least 34 contiguous amino acids of SEQ ID NO:2.
20. A polypeptide comprising at least 51 contiguous amino acids of SEQ ID NO:2.
- 5 21. A peptide comprising about 10 contiguous amino acids of SEQ ID NO:19 or SEQ ID NO:21.
22. The peptide of claim 21, comprising about 15 contiguous amino acids of SEQ ID NO:19 or SEQ ID NO:21.
- 10 23. The peptide of claim 21, comprising about 20 contiguous amino acids of SEQ ID NO:19 or SEQ ID NO:21.
24. The peptide of claim 21, comprising about 25 contiguous amino acids of SEQ ID NO:19 or SEQ ID NO:21.
- 15 25. The peptide of claim 21, comprising about 30 contiguous amino acids of SEQ ID NO:19 or SEQ ID NO:21.
- 20 26. The peptide of claim 21, comprising about 50 contiguous amino acids of SEQ ID NO:19 or SEQ ID NO:21.
27. An expression cassette comprising a polynucleotide encoding a polypeptide having the sequence of SEQ ID NO:2, SEQ ID NO:19 or SEQ ID NO:21, wherein said polynucleotide is under the control of a promoter operable in eukaryotic cells.
- 25 28. The expression cassette of claim 27, wherein said promoter is heterologous to the coding sequence.
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29. The expression cassette of claim 28, wherein said promoter is an inducible promoter.
- 5 30. The expression cassette of claim 28, wherein said expression cassette is contained in a viral vector.
31. The expression cassette of claim 28, wherein said viral vector is selected from the group consisting of a retroviral vector, an adenoviral vector, and adeno-associated viral vector, a vaccinia viral vector, and a herpesviral vector.
- 10 32. The expression cassette of claim 27, wherein said expression cassette further comprises a polyadenylation signal.
33. The expression cassette of claim 27, wherein said expression cassette comprises a second polynucleotide encoding a second polypeptide.
- 15 34. The expression cassette of claim 33, wherein said second polynucleotide is under the control of a second promoter.
- 20 35. The expression cassette of claim 27, wherein the polynucleotide is positioned, in reverse orientation, under the control of a promoter that directs expression of an antisense product.
- 25 36. A cell comprising an expression cassette comprising a polynucleotide encoding a polypeptide having the sequence of SEQ ID NO:2, SEQ ID NO:19 or SEQ ID NO:21, wherein said polynucleotide is under the control of a promoter operable in eukaryotic cells.
- 30 37. A hybridoma cell that produces a monoclonal antibody that binds immunologically to a polypeptide having the sequence of SEQ ID NO:2, SEQ ID NO:19 or SEQ ID NO:21, or an immunologic fragment thereof.

38. A monoclonal antibody that binds immunologically to a polypeptide having the sequence of SEQ ID NO:2, SEQ ID NO:19 or SEQ ID NO:21, or an immunologic fragment thereof.
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39. The monoclonal antibody of claim 38, wherein the antibody further comprises a detectable label.
40. The monoclonal antibody of claim 39, wherein the label is selected from the group consisting of a fluorescent label, a chemiluminescent label, a radiolabel and an enzyme.
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41. A polyclonal antisera, antibodies of which bind immunologically to a polypeptide having the sequence of SEQ ID NO:2, SEQ ID NO:19 or SEQ ID NO:21, or an immunologic fragment thereof.
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42. A method of diagnosing a cancer comprising the steps of:
- (i) obtaining a tissue sample from a subject; and
- 20 (ii) assessing the expression of a headpin nucleic acid or a headpin polypeptide in cells of said sample.
43. The method of claim 42, wherein said cancer is selected from the group consisting of head and neck, brain, lung, liver, spleen, kidney, lymph node, small intestine, pancreas, blood cells, colon, stomach, breast, endometrium, prostate, testicle, ovary, skin, esophagus, bone marrow and blood cancer.
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44. The method of claim 42, wherein said cancer is head and neck cancer.
- 30 45. The method of claim 42, wherein said assessing comprises assaying for a headpin nucleic acid from said sample.

46. The method of claim 45, further comprising subjecting said sample to conditions suitable to amplify said nucleic acid.
- 5 47. The method of claim 42, wherein said assessing comprises contacting said sample with an antibody that binds immunologically to a headpin polypeptide or peptide.
48. The method of claim 47, further comprising subjecting proteins, polypeptides or peptides of said sample to ELISA.
- 10 49. The method of claim 42, further comprising the step of comparing the expression of a headpin nucleic acid, polypeptide or peptide with the expression of headpin in non-cancer samples.
- 15 50. The method of claim 42, wherein assessing involves evaluating the structure of the headpin gene or transcript.
51. A method for treating subject with cancer comprising the step of administering to said subject a headpin proteinaceous composition.
- 20 52. The method of claim 51, wherein said tumor cell is derived from a tissue selected from the group consisting of head and neck, brain, lung, liver, spleen, kidney, lymph node, small intestine, blood cells, pancreas, colon, stomach, breast, endometrium, prostate, testicle, ovary, skin, esophagus, bone marrow and blood
- 25 tissue.
53. The method of claim 52, wherein the subject is a human.
54. A method for treating a subject with cancer comprising the step of administering to said subject a nucleic acid (i) encoding a headpin protein, polypeptide or peptide and (ii) a promoter active in eukaryotic cells, wherein said promoter is
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operably linked to the region encoding said headpin protein, polypeptide or peptide.

- 5 55. The method of claim 54, wherein said tumor cell is derived from a tissue selected from the group consisting of head and neck, brain, lung, liver, spleen, kidney, lymph node, small intestine, blood cells, pancreas, colon, stomach, breast, endometrium, prostate, testicle, ovary, skin, head and neck, esophagus, bone marrow and blood tissue.
- 10 56. The method of claim 54, wherein said promoter is an inducible promoter.
57. The method of claim 54, wherein said expression cassette is contained in a viral vector.
- 15 58. The method of claim 57, wherein said viral vector is selected from the group consisting of a retroviral vector, an adenoviral vector, and adeno-associated viral vector, a vaccinia viral vector, and a herpesviral vector.
- 20 59. The method of claim 54, wherein said expression cassette further comprises a polyadenylation signal.
60. The method of claim 54, wherein said expression cassette comprises a second polynucleotide encoding a second polypeptide.
- 25 61. The method of claim 60, wherein said second polynucleotide is under the control of a second promoter.
62. The method of claim 54, wherein the subject is a human.
- 30 63. A nucleic acid detection kit comprising, in suitable container means, at least a first isolated mammalian headpin nucleic acid segment and a detection reagent.

64. An immunodetection kit comprising, in suitable container means, at least a first antibody that binds to a mammalian headpin protein, polypeptide, or peptide and a detection reagent.

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65. A method for identifying a candidate substance that modulates mammalian headpin activity, comprising the steps of:

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(a) admixing a mammalian headpin composition that comprises a candidate substance, a serine protease, and a mammalian headpin protein, polypeptide or peptide; and

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(b) determining the ability of said candidate substance to modulate the ability of said mammalian headpin protein, polypeptide or peptide to inhibit said serine protease.